K073184

Bausch & Lomb

FEB 21

**510(k) Summary Statement**
**BOSTON RGP Lenses Wet Shipped in Boston SIMPLUS® Multi-Action Solution and Stored for up to 30 Days**


**Applicant's Name and Address**

Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609

**Contact Person**

Debra Ketchum
Manager, Regulatory Affairs
Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609
(585) 338-8638
Debra_Ketchum@bausch.com


**1. Identification of device**

| | |
|---|---|
| Common Name: | flouro silicone acrylate and silicone acrylate rigid gas permeable contact lens materials |
| Trade Name: | BOSTON Contact Lens Materials |
| Classification Name: | Rigid Gas Permeable (hydrophobic) Contact Lens Material |
| Device classification: | Class II 886.5916 |
| Pro Code: | HQD |

**2. Description of device**

BOSTON RGP Contact Lenses are composed of silicone acrylate or fluoro silicone acrylate copolymers wet shipped in Boston SIMPLUS® Multi-Action Solution and stored up to 30 days.

BOSTON SIMPLUS® Multi-Action Solution, a sterile, aqueous, buffered solution that contains poloxamine, hydroxyalky phosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with polyaminopropyl biguanide (0.0005%), chlorhexidine gluconate (0.003%).

**3. Intended use**

BOSTON XO (hexafocon A), BOSTON EO (enflufocon B), BOSTON ES (enflufocon A), BOSTON 7 (satafocon A), and BOSTON RXD (itabisfluorofocon A RGP Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes. The lens may be disinfected using a chemical disinfecting system only.

BOSTON IV (itafocon B), BOSTON II (itafocon A) RGP Contact Lenses are indicated for daily wear for the correction of visual acuity for non-aphakic persons with myopia,

hyperopia, or keratoconus and for the correction of corneal astigmatism up to 4.00 diopters. The lens is disinfected using a chemical (not heat) disinfection system recommended in the labeling.

**4. Substantial Equivalence**

| 510(k) | Clearance Date | Device Description |
|---|---|---|
| K002025 | 10/31/2000 | BOSTON RGP Lenses Wet Shipped in Boston Advance Comfort Formula Conditioning Solution and Stored for Up to 30 Days |

BOSTON RGP Lenses Wet Shipped in Boston Advance Comfort Formula Conditioning Solution and Stored for up to 30 Days has been selected as the predicate device for the Bausch & Lomb BOSTON RGP Lenses to be labeled and stored in BOSTON SIMPLUS® Multi-Action Solution for up to 30 days in which the predicate and substantially equivalent clearance was made under K002025 on 10/31/2000. All identified BOSTON RGP contact lenses are included for labeling with wet storage using BOSTON SIMPLUS® Multi-Action Solution and there is no change in indication for use, nor a change in manufacturing.

**5. Safety and Perfomance Testing:**

**Performance Testing- Microbiology:**

Shelf-Life Testing: Determination of shelf-life for the recommended period of 30 days for storage of Boston fluorosilicone acrylate (FSA) and silicone acrylate (SA) classes of gas permeable lenses as stored in Boston SIMPLUS® Multi-Action Solution was conducted. The representative FSA lens was the Boston Equalens II RGP Contact Lens. The representative SA lens was the BOSTON IV RGP Contact Lens. Testing demonstrated stability as to physical and optical properties in accordance with testing conducted under ISO 11987: 1997 Ophthalmic Optics- Determination of Shelf-life; WI0523 GP Lens Wet Packaging Qualification Procedures. Results support a wet packaging shelf-life of 30 days for SA and FSA GP lenses.

Bioburden Testing: Testing was conducted in accordance with internal procedures to compare bioburden levels of examples of SA and FSA lenses at day 30 as stored at ambient temperatures. Results indicated that bioburden levels were below the required minimum cfu values (<100 cfu / lens).

**6. Packaging**

Bausch & Lomb BOSTON SIMPLUS® Multi-Action Solution will be placed in the lens packages for wet shipping and storage from the laboratory with accompanying labeling instructions with each shipment.

**7. Clinical Data:**

Clinical data is not necessary to support the wet shipment of silicone acrylate (SA) and fluoro silicone acrylate (FSA) GP lenses. Testing has been conducted to demonstrate

that lenses shipped wet maintain their optical and physical parameters within their release specifications and bioburden levels are maintained well within the acceptable bioburden limit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Bausch & Lomb, Inc.
c/o Debra Ketchum
1400 North Goodman Street
Rochester NY 14609-3547

Re: K073184
Trade/Device Name: Boston RGP Lenses Wet Shipped in SIMPLUS® Multi-Action Solution and Stored for up to 30 Days
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD
Dated: November 8, 2007
Received: November 13, 2007

Dear Ms. Ketchum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## SECTION 4 : INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K073184

Device Name: BOSTON RGP Lenses Wet Shipped in BOSTON SIMPLUS® Multi-Action Solution and Stored for Up To 30 Days.

Indication for Use

BOSTON XO (hexafocon A), BOSTON EO (enflufocon B), BOSTON ES (enflufocon A), BOSTON 7 (satafocon A), and BOSTON RXD (itabisfluorofocon A RGP Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes. The lens may be disinfected using a chemical disinfecting system only.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the –counter-use _____

(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K073184